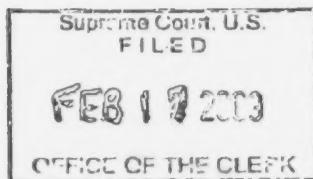


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No. 08-918



IN THE
Supreme Court of the United States

R.J. REYNOLDS TOBACCO COMPANY,
Petitioner,
v.

STAR SCIENTIFIC, INC.,
Respondent.

*On Petition for a Writ of Certiorari to the United
States Court of Appeals for the Federal Circuit*

REPLY FOR PETITIONER

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES.....	ii
REPLY FOR PETITIONER	1
I. THE DECISION BELOW IS SHARPLY AT ODDS WITH MOST DECISIONS OF THE FEDERAL CIRCUIT AND THOSE OF OTHER CIRCUITS ADDRESSING PROOF OF INTENT IN INEQUITABLE CONDUCT.....	4
II. THE FEDERAL CIRCUIT HAS VIO- LATED THIS COURT'S PRECEDENTS ON APPELLATE REVIEW OF TRIAL COURT FACTFINDING.....	8
CONCLUSION	12

TABLE OF AUTHORITIES

	Page
CASES	
<i>Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.</i> , 525 F.3d 1334 (Fed. Cir. 2008)	6
<i>Dennison Manufacturing Co. v. Panduit Corp.</i> , 475 U.S. 809 (1986)	10
<i>Digital Equipment Corp. v. Diamond</i> , 653 F.2d 701 (1st Cir. 1981).....	7
<i>eBay Inc. v. MercExchange, L.L.C.</i> , 547 U.S. 388 (2006).....	10
<i>Ferring B.V. v. Barr Laboratories, Inc.</i> , 437 F.3d 1181 (Fed. Cir. 2006).....	5, 6
<i>Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.</i> , 535 U.S. 826 (2002)	7
<i>Praxair, Inc. v. ATMI, Inc.</i> , 543 F.3d 1306 (Fed. Cir. 2008)	5
<i>Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.</i> , 324 U.S. 806 (1945)	10
<i>True Temper Corp. v. CF&I Steel Corp.</i> , 601 F.2d 495 (10th Cir. 1979)	7
<i>Zenith Radio Corp. v. Hazeltine Research, Inc.</i> , 395 U.S. 100 (1969)	10

REPLY FOR PETITIONER

The Petition for Certiorari demonstrates that the Federal Circuit reversed the district court by attacking a straw man, and by completely ignoring the district court's actual reasoning. Citing almost exclusively to the Federal Circuit decision, the Brief in Opposition now argues against certiorari by again misstating the actual reasoning of the district court, just as the Federal Circuit did. Opp. 8.

The concluding section of the trial court's opinion, Pet. App. 70a-76a, explains its reasons for finding inequitable conduct based on a consistent pattern of actions taken over an extended period:

There is no doubt that throughout the process of prosecution of the Patents-in-Suit, Williams and others kept critical information from the PTO so as to give the false impression that, as of the time of the application leading to the Patents-in-Suit, there had been no curing processes used in the United States that was capable of producing tobacco with low levels of TSNA.

Pet. App. 71a; *id.* at 72a-73a (summarizing actions taken). As discussed at length in the petition, Pet. 6-12, 32-34, the district court's conclusion was fully supported by evidence and specific findings concerning Williams' knowledge of highly material information,¹ and the various acts and omissions by which

¹ Williams admitted knowing no later than September 15, 1998—the date on which false statements were submitted in the provisional '649 application—that long-used curing methods in the United States could produce low or undetectable TSNA levels. App. A290. Indeed, Star's trial counsel in closing

he and others kept that information from the PTO.² It was also supported by several very significant credibility findings, likewise ignored by the Federal Circuit, on the basis of which the trial court ex-

told the court that "everyone involved" in pursuing the patent knew that "[y]ou can get undetectable TSNAs" with existing methods, App. A422, and the trial court so found, Pet. App. 71a.

Notwithstanding these clear admissions, Star and the Federal Circuit focus narrowly on whether the Burton letter itself should have been disclosed. Pet. App. 17a-19a; Opp. 8-9, 12, 15. This singular focus ignores the district court's finding that the critical non-disclosure was not the Burton letter, but "the essential fact" that existing curing methods could produce tobacco with low TSNAs. Pet. App. 71a. Thus, while Star was wrong in denying the existence of any evidence showing that Williams was aware of the Burton letter, Opp. 17; *see* Pet. 6 (testimony cited), that denial also misses the point.

² The Petition summarizes the ample record evidence showing that Williams, among other things, (a) misstated the facts about this prior art to his own counsel, Pet. 6-7; (b) caused the provisional application for the '649 patent to include a false statement about the TSNA levels resulting from existing methods, Pet. 7; (c) caused the non-provisional application for the '649 patent to omit reference to the low TSNA levels produced despite referencing the very prior art techniques in question, Pet. 7-8; and (d) failed to disclose the same facts in a variety of other instances when he should have done so, including in a "Petition to Make Special," which carries a heightened disclosure obligation, Pet. 8-9, in a personal interview with the patent examiner, Pet. 9, and throughout the prosecution of the related '401 patent, Pet. 9-10.

pressly discounted testimony offered to justify the failure to disclose the information.³

Rather than attacking the trial court's reliance on a pattern of actions taken over a period of four years that denied the PTO highly material information, the panel wrongly asserted that the deceptive intent finding was "based primarily on" Star's decision to change legal counsel during the patent prosecution. Pet. App. 17a. Though the trial court opinion mentioned this episode only in discussing background facts, *id.* at 54a, and not in its statement of reasons for its ruling, *id.* at 70a-76a, to the Federal Circuit this was the critical basis for district court's ruling. It thus reversed the finding of deceptive intent, based on its finding of insufficient evidence to show that the law firm switch was made in order to conceal the Burton letter. *Id.* at 21a.

³ The Opposition asserts that the district court ignored testimony supporting Star's decision not to disclose the Burton letter. Opp. 15, 18. To the contrary, the trial court concluded that there was "no valid justification for failing to make the disclosure," Pet. App. 68a, and stated its reasons for rejecting the contrary testimony of Star's witnesses. The trial court found "substantial doubt as to the professional independence" of the patent lawyers involved in the decision, because they were biased by the promise of stock-options to be received only if the patent issued. *Id.* at 70a. It also found suspect the testimony of Star's lead trial lawyer, McMillan, who would receive a substantial contingent fee depending on the outcome of the case. *Id.* at 70a n.16. The district court also discounted the testimony of Dr. Burton, because Star had endowed an academic chair in his name, "paid him a retainer more than his annual salary regardless of any work product produced, and gave Burton hundreds of thousands of dollars in stock options." *Id.* at 69a. The court below mentioned none of this.

In addition to wholly ignoring the trial court's actual reasoning, the court below expatiated on the "need to strictly enforce the burden of proof" of inequitable conduct by clear and convincing evidence "because the penalty for inequitable conduct is so severe," and to "be vigilant in not permitting the defense to be applied too lightly." Pet. App. 13a-14a. It also discussed at length the proposition that materiality and intent are separate requirements that must each be proven separately. *Id.* at 14a-15a.

It thus appears that the panel deliberately gave no weight at all to the trial court's central reliance on the materiality of undisclosed information and its concealment for four years. In doing so, the decision exemplifies an ongoing division within the Federal Circuit on precisely that issue. As shown in the petition, Pet. 18-23, and acknowledged by Star, Opp. 11-13, the predominant view expressed in the circuit's decisions has been that materiality of withheld information is relevant evidence of intent. By treating the trial court's actual reasoning as irrelevant—even unworthy of mention in this case—the panel applied the formerly dissenting approach of some of the court's judges. It also contravened settled authority from this Court regarding the proper roles of fact-finders and appellate courts.

I. THE DECISION BELOW IS SHARPLY AT ODDS WITH MOST DECISIONS OF THE FEDERAL CIRCUIT AND THOSE OF OTHER CIRCUITS ADDRESSING PROOF OF INTENT IN INEQUITABLE CONDUCT

1. Star concedes that Federal Circuit decisions have "considered materiality in assessing intent," Opp. 11, as "a specific application of the common-

place principle that intent may be inferred from circumstantial evidence," Opp. 12. Star also acknowledges that the Federal Circuit has even held that materiality may reduce the required showing from actual intent to a mere "should have known" standard. Opp. 11. *See, e.g., Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006); *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-15, 1318 (Fed. Cir. 2008). This "should have known" standard sharply contrasts with the Federal Circuit's analysis in this case. Pet. 16-21.

Star's assertion that the decision below is nothing new rests on a futile claim that the panel actually gave weight to the trial court's reasoning based on the materiality of the information concealed. Opp. 12-13. A brief review of the decision shows this is plainly false.

The trial court focused on the fact that Williams was concededly well aware that prior curing methods were "capable of producing low-TSNA tobacco." Pet. App. 72a. It found that known information to be "manifestly material" because the alleged invention was itself aimed at consistently achieving precisely that goal. *Id.*⁴ The trial court then found that Reynolds had proved intent to deceive, because Williams and others had "engaged in a consistent scheme to avoid informing the Patent Office that the prior art could produce low TSNA tobacco." *Id.* The district

⁴ This information would be of obvious interest to the PTO because, as Star has acknowledged, at the time of the patent prosecution, "relatively little was known about specific TSNA levels achievable with other curing methods." Star Opening Brief at 14, *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357 (Fed. Cir. 2008) (No. 2007-1448).

court thus noted a pattern of conduct, running from an express falsehood submitted to the PTO on Williams' direction in September 1998, through issuance of the '401 patent in July 2002, *id.* at 72a-75a. This chain of events supported a finding of deceptive intent precisely because it is unreasonable to suppose such obviously material information could have been withheld for so long by accident, without deceptive intent.

Star appears to argue that because the Federal Circuit did not reverse the trial court's finding of materiality, it necessarily evaluated the relevance of materiality in its decision. Opp. 13. But the panel made no reference at all to the trial court's actual reasoning, and certainly offered no reason to doubt its validity. Rather, the Federal Circuit discussed extensively the general obstacles standing in the way of an inequitable conduct finding in any case, including the need for separate findings of both intent and materiality. Pet. App. 13a-16a. It then reversed after a detailed discussion focusing solely on the change of law firms. *Id.* at 17a-22a.

In thus giving no weight as evidence of intent to the fact that highly material information was withheld for a long time, the panel follows several opinions of individual Federal Circuit judges who objected to “[m]erging intent and materiality” by considering the latter to be evidence of the former. *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting); see also, e.g., *Ferring*, 437 F.3d at 1196 (Newman, J., dissenting). Application of this blinded approach in the future would make proof of

deceptive intent exceedingly difficult in any but the most obvious cases.

2. Star does not deny that regional courts of appeals have held, contrary to the Federal Circuit, that actual intent to deceive is not even a required element of inequitable conduct. *See, e.g., Digital Equip. Corp. v. Diamond*, 653 F.2d 701, 709 (1st Cir. 1981); *True Temper Corp. v. CF&I Steel Corp.*, 601 F.2d 495, 501, 504-05 (10th Cir. 1979). It attempts to diminish the significance of this circuit split by claiming that current Federal Circuit authority has effectively abrogated these precedents. Opp. 15-16.

However, this Court has recently affirmed the continuing relevance of regional circuit precedent in some cases including patent claims. *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 834 (2002). And Justice Stevens noted that these regional circuit cases involving patent issues can give rise to circuit splits warranting this Court's review. *Id.* at 839 (Stevens, J., concurring in part and in the judgment).

That fact is not undermined by Star's citation of district court decisions applying the Federal Circuit intent rule. Opp. 16. These cases were all appealable to the Federal Circuit and therefore governed by Federal Circuit law. Thus, they say nothing about the standards governing district court cases where patent issues arise in counterclaims under *Holmes Group*.⁵

⁵ Star's argument, Opp. 16-17, that this Court has denied previous petitions for certiorari raising this inter-circuit split is also unavailing. First, this case presents not only a stark inter-circuit split, but also a deep division over the standards govern-

Finally, Star's argument that "there was no inequitable conduct here under any standard," Opp. 17, again rests upon Star's fundamental mischaracterization of this case. Star falsely asserts that the district court's finding of intent was predicated on three discrete facts, not the wide ranging pattern of conduct over a period of years upon which the district court actually relied. Moreover, Star's argument that the information withheld was in fact immaterial, even though the court below left standing the materiality finding, is patently false. Try as Star does to characterize the withheld information as a single letter, the trial court made clear that the concealment was of the "essential fact" that existing curing methods were capable of "the production of tobacco with low to undetectable levels of TSNA"—the precise objective of Williams' purported invention. Pet. App. 71a; *see supra* note 1.

II. THE FEDERAL CIRCUIT HAS VIOLATED THIS COURT'S PRECEDENTS ON APPELLATE REVIEW OF TRIAL COURT FACTFINDING

1. By reversing the trial court's holding of deceptive intent without mentioning it or offering any rea-

ing the intent inquiry within the Federal Circuit that had not yet ripened when those petitions were filed. Second, the practical importance of the circuit split is far greater now that the Federal Circuit has applied its own approach to the intent inquiry in an extreme and unjustified manner that would contravene basic principles of trial court factfinding and appellate review, as discussed more fully in the next section.

son to doubt its soundness, the Federal Circuit flagrantly violated this Court's directives about appellate review of factfinding. Star's only response is to claim that the panel actually considered the trial court's reasoning, including the materiality of the withheld information. Opp. 19-20. This claim is plainly false.

Star notes the statement of the panel that "intent can be inferred from indirect and circumstantial evidence," and baldly asserts that the court "went on to assess the circumstantial evidence from which the district court inferred improper intent. [Pet. App.] at 17a-22a." Opp. 19-20. While the court did give lip service to the relevance of circumstantial evidence, it most assuredly did not consider or even mention the evidence or inferential reasoning on which the trial court actually relied.

All of the discussion leading to reversal of the finding of deceptive intent focused on the change-of-law-firm incident. The referenced section begins with the assertion that the trial court's intent finding "was based primarily on" that incident. Pet. App. 17a. After four pages devoted solely to that subject, the court held the intent finding clearly erroneous, "[g]iven the heavy reliance by the district court on the . . . [law firm] 'quarantine' theory [and] the numerous evidentiary failings relating to this theory." *Id.* at 21a.

The gist of the Federal Circuit's reasoning is that there was inadequate proof of a conspiracy to switch law firms for the purpose of concealing the Burton letter, and, *on that basis*, the deceptive intent finding was erroneous. Following the court's admonitions about the need for separate consideration of

materiality and intent, Pet. App. 13a-16a, there is no mention anywhere in the opinion of the simple inference on which the trial court rested: That Williams and others knew early on that prior art methods could achieve very low TSNA tobacco—the very goal of their invention—yet never over several years disclosed that highly material fact to the PTO.

Star's only other response is to dismiss this Court's cases as irrelevant because they did not occur in the patent context. Opp. 20-21. This distinction flies in the face of this Court's repeated warnings, Pet. 27-30, that ordinary principles of this Court's jurisprudence cannot be discarded in the patent context without some valid rationale. *See, e.g., eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

In any event, this Court has applied the same principles regarding circumstantial evidence in the inequitable conduct context. Pet. 28-29. Star dismisses *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814-19 (1945), in a single, vaguely worded sentence noting that it was an "early" case, and that the discussion of the facts was "a necessary incident to discussion of the legal standard." Opp. 22-23. Whatever that may mean, it does not change the fact that *Precision Instrument* found the evidence in that case sufficient to show inequitable conduct using ordinary inferences from the totality of the facts.

Star's dismissals of *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100 (1969), and *Dennison Manufacturing Co. v. Panduit Corp.*, 475 U.S. 809 (1986) (per curiam), are similarly terse and devoid of reasoned argument. Opp. 23. Star does not dispute the relevant fact about both cases—that this

Court applied the same principles that Star dismisses as irrelevant to the patent-law context.

2. Star also offers no basis to contest that the panel below contravened this Court's precedents regarding the appellate review of factfinding. Star says only that the panel alluded to the clear error standard of review and purported to apply it. Opp. 21. But for all of the reasons set forth above, and in the petition, Pet. 25-27, the court's blatant refusal to acknowledge the actual reasoning of the trial court renders its application of the clear error standard a sham. It is simply impossible that the Federal Circuit paid proper deference to factual findings that it did not even mention or show any reason to question.

3. Finally, Star offers virtually no response to Reynolds' showing that the issues in this case are of great importance and urgency, warranting this Court's review. Pet. 30-32. Star merely argues that the constitutional foundation for the patent system is irrelevant because "[n]ot every patent case merits this Court's review." Opp. 23. Reynolds showed, however, that this case warrants review not simply because it is a patent case, but because it announced an approach that will have far-reaching and grave ramifications for the patent system, and will undermine the constitutional bedrock upon which the patent system rests. If courts in future cases follow the example of the Federal Circuit in denying any consideration to the materiality of undisclosed information—and the panel's soliloquy on the need to keep materiality and intent separate may well cause them to do so—then patents will routinely be permitted to issue in the face of deception, nondisclosure, and

other misconduct by patent applicants. Such a serious threat to the operation of the patent system plainly warrants this Court's review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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